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Attorney Docket N . 21486-032
 DIV1



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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT : Wands et al.
 SERIAL NUMBER : 09/903,023
 FILING DATE : July 11, 2001
 FOR : DIAGNOSIS AND TREATMENT OF MALIGNANT NEOPLASMS

EXAMINER : Yu, Misook
 ART UNIT : 1642

Assistant Commissioner for Patents
 Washington, D.C. 20231

September 25, 2003
 Boston, Massachusetts

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 TECH CENTER 1600/2900
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DECLARATION OF MICHAEL S. LEBOWITZ UNDER 37 C.F.R §1.132

I, Michael S. Lebowitz, declare and state as follows:

1. I am employed by Panacea Pharmaceuticals, Inc., licensee of the technology claimed by the patent application referenced above. I am a principal investigator on projects involving neurodegenerative disorders and cancer.

2. I received a B.S. degree from the Brandeis University in 1989 and a Ph.D. in Biological Chemistry from The Johns Hopkins University School of Medicine in 1995.

3. I have read the Office Action mailed on March 26, 2003 and am familiar with the Examiner's grounds of rejection of the pending claims.

Wands et al.
09/903,023

4. A serum-based HAAH sandwich ELISA was used to analyze an expanded panel of human sera. The panel included 85 sera from individuals diagnosed with cancer and 230 sera from individuals lacking a diagnosis of cancer. In 223 of the 230 non-cancerous (normal) serum samples, no HAAH was detected by the assay. HAAH was detected in the seven remaining samples. It is possible that the values are artifactual or that these individuals do in fact have an as yet undetected tumor. Thus, the specificity of the assay is 97%. The relative sensitivities for different cancer types are listed in Table II. The overall sensitivity of the assay for detection of cancer relative to non-cancer (normal) is 94%. These data indicate that malignant neoplasms are reliably diagnosed by detecting an increase of HAAH in a bodily fluid compared to non-cancerous (normal) values using an antibody which binds to HAAH.

Table I: Detection of HAAH in Human Sera

Serum Samples	Positive/Total	Sensitivity
<i>Normal</i>	7/230	
Breast Cancer	8/9	89%
Ovarian Cancer	8/8	100%
Prostate Cancer	8/8	100%
Colon Cancer	5/5	100%
Esophageal Cancer	6/6	100%
Bladder Cancer	24/24	100%
Kidney Cancer	21/25	84%
Total Cancer	80/85	94%

Overall Assay
Specificity: 97% (n-230)
Sensitivity: 94% (n=85)

5. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by a fine or imprisonment, or both, under Section 1001 of Title 18 of the

Wands et al.
09/903,023

United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date 9/25/03



Michael S. Lebowitz, Ph.D.

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